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APPUCATION NUMBER SEE FILING PATE 1 SIZES EXECUTIVES EXECUTIVE TO SEE AN ERST NAMED APPLICANT ATTY DOCKET, NO. 1

HM32/0805

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EXA	MINER
CRANE, L	
ART UNIT	PAPER NUMBER
1623	5

DATE MAILED:

08/05/98

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This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS

-3	Responsive to communication(s) filed on July 29, 1998 & May 13, 1998
]	This action is FINAL.
J	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 D.C. 11; 453 O.G. 213.
hi ne	nortened statutory period for response to this action is set to expire3
ls	position of Claims
¥	Claim/s) 18-31is/are pending in the application
3-	Claim(s) 18-31is/are pending in the application. Of the above, claim(s)is/are withdrawn from consideration.
ķ	Claim(s)
]	Claim(s)is/are objected to. Claim(s)are subject to restriction or election requirement.
]	Claim(s) are subject to restriction or election requirement.
] Claims 1-17 have been cancelled.
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J	See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed an
_	The drawing(s) filed onis/are objected to by the Examiner. The proposed drawing correction, filed onis approved disapproved.
╡	The specification is objected to by the Examiner.
₹	The oath or declaration is objected to by the Examiner.
_	· · · · · · · · · · · · · · · · · · ·
ric	ority under 35 U.S.C. § 119
æ	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
Æ	☑ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
	XX received.
	received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
4	Certified copies not received:
]	Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).
tte	achment(s)
1.	Notice of Reference Cited, PTO-892
_	Information Disclosure Statement(s), PTO-1449, Paper No(s), 3 & 5
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ز	Notice of Draftperson's Patent Drawing Review, PTO-948
-	Notice of Informal Patent Application, PTO-152

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

Claims 1–17 have been cancelled as per the amendments filed July 28, 1998 and May 13, 1998. Applicant's indicate of a claim 18 subject to cancellation is deemed to be in error as only seventeen claims appear to be in the instant case. As a consequence, newly submitted claims 19–32 have been renumbered as 18-31, respectively, under the authority of 37 C.F.R. §1.126.

Claims 18-31 remain in the case.

Claims 18-31 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, lines 1, 9 and 18, the term "comprising" and at line 4, the term "including" are improper because the noted term of art and its synonym both refer to chemical compounds of known or knowable structure in a manner which implies that the structural subject matter of the claim includes ancillary chemical structures not defined therein, i.e. that the claim is indefinite. Applicant is respectfully requested to substitute for the noted terms a term of art which has definite metes and bounds such as — consisting of — or the like. The same problem occurs in claim 23 line 1; claim 26, line 1; claim 27, line 1; and, claim 28, line 1.

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In claim 18, at lines 16–25, functional language used to describe the mechanism of what appears to be an oligonucleotide chain cleavage-from-a-solid-support reaction is helpful in understanding the utility of the claimed invention, but fails along with the remainder of the claim to provide a clear set of metes and bounds (defined chemical structural elements) of what applicant has claimed. Applicant is respectfully requested to define the instant chemical substance with detailed chemical formula(s) as appropriate and simultaneously to delete process limitations. Additionally, applicant may chose to claim multiple different chemical species to simultaneously obtain coverage for the claimed invention and illustrate the various intermediate chemical structures (but not mechanistic intermediates) alluded to in the instant claim.

In claim 18, lines 6-7, it is unclear based on a reading of the noted lines exactly what meaning applicant intends to convey. Perhaps applicant could use the term — groups inert to solid phase nucleic acid synthesis conditions — in place of the longer term beginning with "inert groups, … ." The same problem reoccurs in claim 23.

In claim 19, the term "heterocyclic formed in part by said adjacent carbon atoms" is unclear as to the specific structural characteristics of the "heterocycle" and therefore does not provide clear metes and bounds for the claimed subject matter. The same problem reoccurs also in claim 29;

In claim **20**, the term "substituted to unsubstituted moiety" is unclear as to the specific structural characteristics of the "moiety"

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and therefore does not provide clear metes and bounds for the claimed subject matter. The same problem occur sin claim 28.

Claims 21 and 22, when compared provide conflicting perspectives on the nature of the "nucleophile." Applicant is respectfully requested to clear up the resultant confusion.

In claim 24, there occurs again very broad functional language similar in vagueness to that of claim 18.

In claims 21-22 and 30-31, it is unclear if the second claim in both pairs of claims is referring to a C-acetyl group or an O-acetyl group.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term, *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "Ac" in claim(s) 24, 25 is used by the claim(s) to mean "acyl", while the accepted meaning is — acetyl —. Applicant may chose to substitute the term —Acyl— (e.g. -NHAcyl, etc.) as the generic substituent and thereby avoid this technical confusion.

Note to applicant: In effect all of the new claims (18–31) have been rejected as a result of applicant's substantial reliance on functional language to describe elements of the instant claimed genus of chemical species. Because of this the instant claims are open to the very broad interpretation of the prior art cited in the art rejections of record. Examiner suggests with all due respect that claims which rely on a more complete structural description using more detailed chemical formulae may give applicant an opportunity to claim in a manner which avoids the prior art. Applicant is also cautioned to avoid process limitations in compound claims. Applicant

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is requested to consider a different claiming strategy wherein a pharmaceutical type of compound claim which includes all of the structural limitations and extensions specified with Markush groups is the independent claim (genus) and dependent claims are subgeneric and/or species claims. This approach in examiner's experience permits avoidance of many of the problems associated herein with 112, second paragraph, as noted above, and the use of what should really be "further comprising" claims to reach the species level.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims 18-20 and 23-27 are rejected under 35 U.S.C. §102(a) as being anticipated by Lyttle et al. (PTO-892 ref S).

The instant claims are directed to compounds which include a function "Nu" which is deemed to read on one or more of the compounds numbered 1, 4 and 5 as disclosed in the Lyttle et al. reference at Fig. 1, col. 1, of p. 2795. Applicant's use of terms like "inert group" and "acyl group" without specification of substituent structures makes the instant claimed subject matter very broad in

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scope and therefore an appropriate target for a finding of anticipatory overlap with prior art of the type cited.

Claims 18-20 and 23-27 rejected under 35 U.S.C. §102(b) as being anticipated by Webb et al. (PTO-892 ref. B).

Applicant is requested to note the description and structure at the bottom of col. 2 and continuing through the middle of column 4, all of which strongly suggest anticipation of applicant's invention.

Claims 18-20 and 23-27 rejected under 35 U.S.C. §102(b) as being anticipated by Nelson et al. (PTO-892 ref. Y).

Applicant is referred to p. 7188, Figure 1 wherein the structure labeled "MF-CPG" (final product) appears to anticipate the instant invention.

Claims 18-20 and 23-27 rejected under 35 U.S.C. §102(b) as being anticipated by Vu et al. (PTO-892 ref. V).

Applicant is referred to p. 604, Figure 1, the compounds labeled with numbers 5, 8, 13, 19, 28 and 32, each of which appears to anticipate applicant's invention as presently disclosed and claimed.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

20 "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

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Claims 21-22 and 28-31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Arnold '866 (PTO-892 ref. E).

The instant claims are directed to compounds which are modified solid supports ribose residues attached thereto as an integral part of the functionality used initially to attach a growing oligonucleotide chain, and following modification and/or deprotection thereof, cleavage of the oligonucleotide from the solid support.

The Arnold '866 patent claims a process for making compounds of the kind apparently envisioned by the instant claims and therein discloses compounds which appear to be encompassed herein by the instant claims. Applicant is referred to the claims in the cited reference. Because the instant claims are presented in language which is large functional, it is unclear whether the instant reference fails to meet any of the limitations of the instant claims.

The prior disclosure of compounds which appear to read on the instant claims is deemed to be sufficient basis for finding that the instant claims lack patentable distinction in view of the cited prior art.

Therefore, the instant claimed compounds as presently understood would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as closely related prior art which shows the state of the relevant prior art.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. \$103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. \$1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. \$\$102(f) or (g) prior art under 35 U.S.C. \$103.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703)** 308-4556 and **703-305-3592**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached at (703)–308–1235.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

Serial No. 09/076,956

Art Unit 1623

LECrane:lec 8/3/98

L. Eric Crane Patent Examiner Group 1600